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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,435	07/17/2003	Janet Codd	DOVP-1-0901	1728

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EXAMINER	
ROGERS, JAMES WILLIAM	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
08/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/621,435	CODD ET AL.	
	Examiner	Art Unit	
	James W. Rogers, Ph.D.	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *10-13,16-18,26-36 and 45-49* is/are pending in the application.

4a) Of the above claim(s) *2-4,6-8,15,19-25 and 37-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *10-13,16-18,26-36 and 45-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 26,29-33,35-36,45,47-49 are rejected under 35 U.S.C. 102(e) as being anticipated by Dietrich et al. (US 2004/0058896 A1), for the reasons expressed in the previous office action dated 02/01/2007.

Response to Arguments

Applicant's arguments filed 02/01/2007 have been fully considered but they are not persuasive.

Applicants argue that Dietrich merely lists hypothetical combinations of polymers and active agents and does not provide pharmaceutical compositions of active agents and polymer ingredients. Applicants also state that Dietrich is purely prophetic and covers such a vast range of compounds that it is essentially not a teaching of applicants claimed invention. Applicants essentially summarize that Dietrich fails to describe or enable applicants claimed invention.

Firstly just because Dietrich is broad in relation to the amount of actives that could be incorporated into the pharmaceutical compositions does not necessarily mean

the reference does not teach or is not enabled for applicants claimed invention. Clearly from Dietrich it is well known that numerous active ingredients are well known to be used in conjunction with excipients such as polymers. One cannot look just at the reference in regards to examples for enablement, rather one must consider the state of the art when enablement is in question. It is well known in the art that pharmaceutical dosage forms such as tablets, granules capsules ect. are comprised of active ingredients for treating/preventing a condition for a subject in need in conjunction with excipient(s) which can act as a carrier or/and to aid in the process of manufacture. From the teachings of Dietrich hydroxypropylmethylcellulose (HPMC) could be used as a polymer excipient and bicifadine could be selected as the active ingredient. It is well known that enumerable pharmaceutical compositions are formed with excipients such as HPMC in conjunction with active ingredients such as bicifadine. Therefore the examiner does not consider that there is an undue burden on someone with skill in the art to find the Dietrich referenced and use it for a guideline to create a pharmaceutical that contains a known polymer excipient such as HPMC and a known active ingredient such as bicfidine. Thus Dietrich is enabled for applicants invention and does adequately describe applicants claimed invention at least as presently amended.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10-13,16-18,26-36,45-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fanshawe et al. (US 4,231,935, disclosed by applicants) in view of Dietrich et al. (US 2004/0058896 A1), for the reasons expressed in the previous office action dated 02/01/2007.

Response to Arguments

Applicant's arguments filed 02/01/2007 have been fully considered but they are not persuasive.

Applicants have shifted the burden to the examiner to identify a suggestion or practical motivation in the art to formulate bicifadine in a sustained release, oral dosage form as provided by applicants. Applicants state that the art of record teaches away form a pharmaceutical composition that provides bicifadine in a sustained release manner which applicants state is not obvious.

The examiner would like to call to the attention the ruling of *KSR International Co. v Teleflex*, which upheld that the test for obviousness is not just suggestion or

motivation but other reasons to combine also exist outside of the teaching, suggestion and motivation standard or TSM. Applicants invention is drawn to an oral dosage form or pharmaceutical composition containing bicifadine and a sustained release vehicle, the sustained release vehicle is claimed in independent/dependent claims as HPMC. When the examiner conducted his search these limitations were considered, the release properties are inherently the same if two compositions are the same. By combination Fanshawe and Dietrich disclose all of applicants claimed limitations, therefore since by combination the two references teach the same composition it will have the same release properties. Applicants have not provided in their arguments where the two references teach that only immediate release dosage form is contemplated. Dietrich does state that the polymers are added to influence the pharmaceutical properties of the individual active ingredients eg delivery of the active ingredient. Since Dietrich teaches the use HPMC as a polymer it will influence the composition in the same manner as applicants claimed invention. Clearly then from the disclosure of Fanshawe it was well known that bicifadine compositions contained excipients, it would be obvious to combine the excipients of Dietrich with Fanshawe. As outlined in the previous action one would be motivated to use the polymers excipients of Dietrich because the compositions within were said to have desirable properties such as a controlled release rate, high stability, good compressibility and a uniform delivery of the active ingredient. The desirable properties above are obviously associated with the excipients contemplated by Dietrich such as HPMC.

Conclusion

No claims are allowed at this time.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 572-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you

have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER